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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,678	09/28/2001	Eric Goutay	PF 100 PCT US	5103
25666	7590	11/18/2004	EXAMINER	
THE FIRM OF HUESCHEN AND SAGE 500 COLUMBIA PLAZA 350 EAST MICHIGAN AVENUE KALAMAZOO, MI 49007			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,678

Applicant(s)

GOUTAY ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-44 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-44 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 4/26/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 26-44, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Derrieu et al (USPN 5,527,783 hereafter 783) and Allen, Jr. et al (USPN 5,595,761 hereafter '761). The claims are drawn to a fast dissolving micro-porous structure.

4. The '783 patent discloses a solid composition based on plants, comprised of an active principle, diluents, binders, coloring and flavors (col. 4, lin. 7-12). The diluents of preference include lactose and mannitol (col. 4, lin. 27-28). The binders include gums such as gum Arabic, alginates, pectins, gelatin, xanthan gum, dextrin and polyvinylpyrrolidone (col. 4, lin 29-39). The additives used in the reference invention are those normally used in the pharmaceutical and food industry and are compatible with the active principles present (col. 4, lin. 39-43). The reference is however silent to the inclusion of a specific pharmaceutical actives. The reference is also silent to the density and dissolution time of the structure.

5. The '761 patent discloses a fast dissolving micro-porous composition comprising gelatin, and other components such as diluents, colors, flavors and binders (col. 6, lin. 60-65). The

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composition included alginic acid, polyvinylpyrrolidone, mannitol, and organic acids (col. 7, lin. 1-10). Further the composition has a density range of 0.1g/ml to 0.6g/ml (col. 4, lin. 1-28), and dissolution below 10 seconds (*Ibid.*). It would have been obvious to include the components of plant origin into the formulation of '761 in order to modulate the dissolution rate. The inclusion of the maltodextrins of '783 would have been well within the level of skill in the art.

Regarding the limitations reciting specific concentrations, it is the position of the examiner that such limitations do not impart patentability. The '761 patent discloses carriers in concentration above 60%, and very low concentrations of binding agents (examples). Though not every concentration is disclosed, the general conditions of the claims are met. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

6. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

7. With these things in mind one of ordinary skill in the art would have been motivated to combine the polysaccharides of '783 with the components and formulation of '761 in order to impart a sweeter flavor onto the formulation. It would have been obvious to combines these

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teachings and suggestions with an expected result of an effervescent formulation useful in delivering active agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600